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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/052,758

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Nicholas deBeer

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08/29/2008

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

08/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/052,758	Applicant(s) DEBEER ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6,8,9,13,14,16,18,19,21,22 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,6,8,9,13,14,16,18,19,21,22 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-29 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. (US Pat. No. 5,853,422) in view of Shaw et al. (US Pat. No. 6,080,182). Huebsch et al. discloses a catheter delivered septal defect occluder comprising: a tubular frame having parallel slits (col. 3, lines 39-44), made of nitinol, a nickel-titanium shape memory alloy, (col. 3, lines 64- col. 4, line 1), with circular biodegradable sheets over each end of the frame (col. 7, lines 44-48), the frames forming umbrellas that bend towards the midpoint of the frame (e.g. Figs. 23 and 24). However, Huebsch et al. does not disclose a self-expanding device. Shaw et al. teaches a device for sealing septal defect that is self-expanding in columns 3, 5, and 6 for the purpose of facilitating the insertion of the device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the device self-expanding in order to facilitate the insertion of the device.

Claims 30 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. in view of Shaw et al, as above, in further view of Goldstein et al. (US Pat. No. 6,143,037). Huebsch et al. and Shaw et al. teach the claimed septal defect occluder, however, they fail to disclose the occluder having a galactide and lactide copolymer member covering at least a portion of the umbrella or disc shaped halves.

Art Unit: 3774

Goldstein et al. teaches a septal defect occluder (col. 31, lines 26-47) having a member (col. 6, lines 33-41) made of a copolymer of glycolic acid and lactic acid (col. 15, lines 37-40) which is useful for targeted local delivery of pharmaceutical agents at a site of medical intervention (col. 1, lines 8-11).

It would have been obvious to one of ordinary skill in the art to combine the teaching of a member made of a copolymer of glycolic acid and lactic acid, as taught by Goldstein et al., to a septal defect occluder as per Huebsch et al. as modified by Shaw et al., for targeted local delivery of pharmaceutical agents at a site of medical intervention. Please Note: a glycolic acid and lactic acid copolymer is a galactide-lactide copolymer as admitted by the Applicant (p 11, lines 7-13).

Response to Arguments

Applicant's arguments filed 5/16/2008 have been fully considered but they are not persuasive. The Huebsch et al. reference, as stated above, does not teach the self-expanding properties claimed by the Applicant. The Shaw et al. reference teaches a similar device that utilizes a self-expanding, shape memory material to construct a device for sealing a defect in a wall. The device also has a fluoropolymer membrane that is supported by an embedded wire structure having elastic properties which is capable of being compressed and inserted in the defect by a catheter and thereafter returning to its memory induced configuration. The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of the primary and the secondary references. In the instant case, the motivation is to make insertion of the device easier by eliminating the need for additional devices by using a self-expanding, shape memory material, as taught by Shaw et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774